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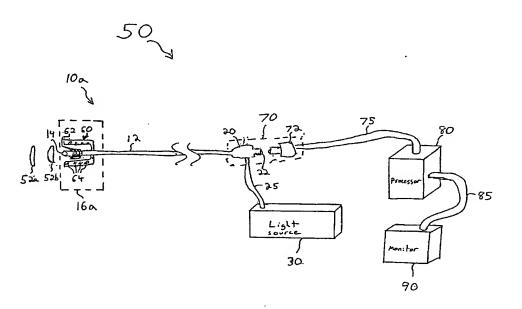
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(54) Title: VISION CATHETER



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(57) Abstract: A catheter with a small optical fiber or bundle of fibers includes a scanning mechanism constructed with the use of any vibration capable component. Magnetic, piezoelectric or other mechanisms are used to vibrate the end of the fiber and thus create a scanning effect which extends the field of view. This configuration can be used in a catheter with a relatively small diameter. A glass lens or lenses placed in front of the fiber focuses and magnifies the image. A CCD, CMOS, or photodiode camera at the proximal end of the fiber captures the image and transfers it to a computer or processor. A light splitter coupled to a light source provides light through an illumination fiber. The resulting vision catheter is relatively inexpensive and disposable.

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#### VISION CATHETER

#### FIELD OF THE INVENTION

The present invention relates to medical devices, and in particular to a catheter with imaging capabilities.

5 BACKGROUND OF THE INVENTION

An endoscope is a type of catheter that has imaging capabilities so as to be able to provide images of an internal body cavity of a patient. Most minimally invasive surgical procedures performed in the GI tract or other internal body cavities are accomplished with the aid of an endoscope. A typical endoscope has an illumination channel and an imaging channel, both of which may be made of a bundle of optical fibers. The illumination channel is coupled to a light source to illuminate an internal body cavity of a patient, and the imaging channel transmits an image created by a lens at the distal end of the scope to a connected camera unit or display device.

As an alternative to an imaging channel made of a bundle of optical fibers, a semiconductor-type camera can also be attached onto the distal tip. One drawback of this alternative is that such cameras are relatively large in size, in comparison to the dimensions needed for certain surgical procedures. Another issue with either the semiconductor-type camera or the bundle of fibers, is that the ability to see a larger area requires moving the camera or the bundle of fibers. This type of movement is relatively complex to implement, and requires even more area. Furthermore, while endoscopes are a proven technology, they are relatively complex and expensive to manufacture.

Given these shortcomings, there is a need for a relatively small imaging device that is inexpensive and disposable.

#### SUMMARY OF THE INVENTION

To address these and other concerns, the present invention is a catheter that includes an imaging channel. The imaging channel may include an optical fiber bundle or a single optical fiber with a distal end and a proximal end. The field of vision of the imaging channel is increased by vibrating the distal end. A number of compact and relatively inexpensive technologies can be used to vibrate the distal end, such as electric coils, piezoelectric crystals, and microelectrical mechanical systems (MEMS). Other types of energy that can be used include ultrasound or frequency modulation.

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In an embodiment utilizing an electrical coil, a metal-type ring or object encases the distal end and is contained in a housing with the electrical coil for vibrating the distal end in a controlled manner. This produces a scanning effect in that as the distal end moves, the field of vision at the distal end effectively increases. In alternate embodiments, the housing may contain other technologies for creating the movement, such as piezoelectric crystals, MEMS, etc. An objective lens or a series of lenses is placed in front of the distal end to magnify the image. A focusing screw mechanism is incorporated so that the image can be focused. At the proximal end, an imaging device such as a CCD, CMOS, pin hole, or photo diode camera is positioned so as to capture and transfer the image to either a processor or a computer that is able to store or display the image. A light processing box is located between the camera and the proximal end, which provides the source for the light that illuminates the imaged area.

It will be appreciated that the vision catheter of the present invention includes components that are widely available and that can easily be assembled. The simple design thus allows for the production of catheters that are relatively inexpensive and disposable and which have imaging capabilities while still remaining relatively small in diameter.

### BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 shows a vision catheter formed in accordance with one embodiment of the present invention; and

FIGURE 2 shows an imaging system including a vision catheter combined with a processor and monitor for displaying a sensed image.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGURE 1 is a diagram of a vision catheter 10 formed in accordance with the present invention. The vision catheter 10 includes a flexible imaging cable 12 having a polished distal end 14. In one embodiment, the flexible imaging cable 12 may include a group of standard clad optical fibers. In general, the optical fibers will include one or

more imaging fibers and one or more illumination fibers. The imaging fibers transmit image information detected at the distal end 14 of the imaging cable 12. The illumination fibers are coupled to a light source so as to provide illumination at the distal end 14 of the imaging cable 12.

The vision catheter 10 also includes a vibration generator 16. In accordance with the present invention, the vibration generator 16 vibrates the distal end 14 of the imaging cable 12. This essentially produces a scanning effect in that as the distal end 14 moves, the field of view that is sensed by the distal end 14 effectively increases. As will be described in more detail below with reference to FIGURE 2, the sensed image may be transferred to a computer or processor, and may further be recorded and/or displayed on a monitor.

The imaging cable 12 also includes a proximal end that is received within a housing 20. The housing 20 also includes a light splitter (not shown) which receives light through a cable 25 from a light source 30. The cable 25 may include a group of standard clad optical fibers that function as illumination fibers for carrying the light from the light source 30 to the light splitter within the housing 20. The light from the light splitter within the housing 20 is provided through the one or more illumination fibers in the imaging cable 12 to the distal end 14 of the imaging cable 12 for illuminating the imaged area. The housing 20 also includes an aperture 22 through which the image signals from the proximal end of the imaging cable 12 can be received.

FIGURE 2 is a diagram of an imaging system 50 including a vision catheter 10a coupled to a processor 80 and a monitor 90. The vision catheter 10a includes a vibration generator 16a. The vibration generator 16a includes a metal ring 62 and electromagnetic coils 64. The metal ring 62 is placed around the imaging cable 12 at the distal end 14, and provides the mechanism for the coils 64 to vibrate the distal end 14 of the imaging cable 12 through the use of electromagnetic energy. In alternate embodiments, other technologies may be utilized in the vibration generator, such as piezoelectric crystals or microelectrical mechanical systems (MEMS). Further types of energy that can be used include ultrasound or frequency modulation.

A series of objective lenses 52a and 52b are placed in front of the imaging cable 12 to focus and magnify the image. A focusing mechanism such as a screw (not shown) may be incorporated so that the image sensed by the imaging cable can be better focused. A housing 70 includes the housing 20 which receives the proximal end of the

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imaging cable 12. The housing 70 also includes an imaging device 72 which is positioned relative to the aperture 22 so as to capture and transfer the image signals from the proximal end of the imaging cable 12. The imaging device 72 may be a CCD, CMOS, pin hole, photodiode camera, or other type camera. The imaging device 72 transfers the image through a cable 75 to a processor 80. The processor 80 may store or display the image. When the image is to be displayed, the processor may provide image signals through a cable 85 to a monitor 90.

It will be appreciated that the present invention provides a vision catheter that is relatively easy to build and which can be made from widely available components. Prior vision systems, such as endoscopes, tended to be relatively complex and expensive. The vision catheter of the present invention is relatively inexpensive and disposable.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention. For example, the imaging cable may incorporate the use of an optical single pixel or multi-fiber glass or plastic imaging bundle. The catheter construction could also include the optical bundle such that it is sandwiched or co-extruded and made to have any number of lumens. Extrusion technology can be used to provide any desired level of variable stiffness, torque, or articulation that is desired.

With regard to the illumination, while the casing at the proximal end of the imaging cable has generally been described as including a light splitter, it will be understood that any appropriate light directing mechanism may be utilized to focus light down to the tip at the distal end of the imaging cable so as to illuminate the imaged area. The light source itself could be replaced with a self-contained white light LED contained within the housing. The intensity of the light could be controlled by software or by a balancing control knob.

With regard to the field of view, focusing, and magnification, the lens or lenses at the distal end of the imaging fiber could be made to be adjustable so as to further increase the field of view or to allow for focus and additional magnification. The lens at the distal tip could be designed to have extra lumens for flushing so as to clean the surface. A focusing screw mechanism could be used to adjust the movement of the fiber for image sharpness and could be controlled by using any focusing technology known in the art. In addition, the vision catheter could be modified to include a mirror, either attached to the

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fiber or separated and appropriately positioned to allow for side viewing of images. By providing a side viewing port for the catheter, this would allow for a catheter with cutting wires to be observed during a surgical procedure.

Additional technologies that could be utilized for the vision catheter include infrared or ultrasound. It will be appreciated that these are just some of the various changes that could be made without departing from the spirit and scope of the invention. Accordingly, the embodiments of the invention, as set forth above, are intended to be illustrative, not limiting.

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The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

#### 1. A vision catheter, comprising:

an image channel comprising one or more imaging fibers and a distal end and a proximal end, the distal end having a field of view of an imaged area; and

a vibration generator for vibrating the distal end, the vibration of the distal end causing the distal end to move relative to the imaged area and thus increase the field of view.

- 2. The vision catheter of Claim 1, wherein the imaging channel comprises an imaging cable and the one or more imaging fibers are optical fibers.
- 3. The vision catheter of Claim 1, further comprising one or more lenses located at the distal end for magnifying the imaged area.
- 4. The vision catheter of Claim 1, wherein the vibration generator comprises a metal ring and one or more electromagnetic coils, the metal ring being placed around the one or more imaging fibers, the electromagnetic coils being driven by electrical energy so as to vibrate the metal ring.
- 5. The vision catheter of Claim 1, further comprising one or more illumination fibers for illuminating the imaged area.
- 6. The vision catheter of Claim 5, further comprising a light source coupled to a light splitter for providing light to the one or more illumination fibers.
- 7. The vision catheter of Claim 1, wherein the proximal end outputs sensed image signals representing the imaged area, and the vision catheter further comprises an imaging device for receiving the sensed image signals from the proximal end.
- 8. The vision catheter of Claim 7, wherein the imaging device is coupled to a processor and monitor that is able to display the image.
- 9. The vision catheter of Claim 7, wherein the imaging device is one of a CCD, CMOS, pin hole, or photodiode camera.

10. A method for using one or more imaging fibers to provide imaging signals during a surgical procedure, the one or more imaging fibers having a distal end and a proximal end, the method comprising:

placing the distal end of one or more imaging fibers proximate to an area of which an image is desired; and

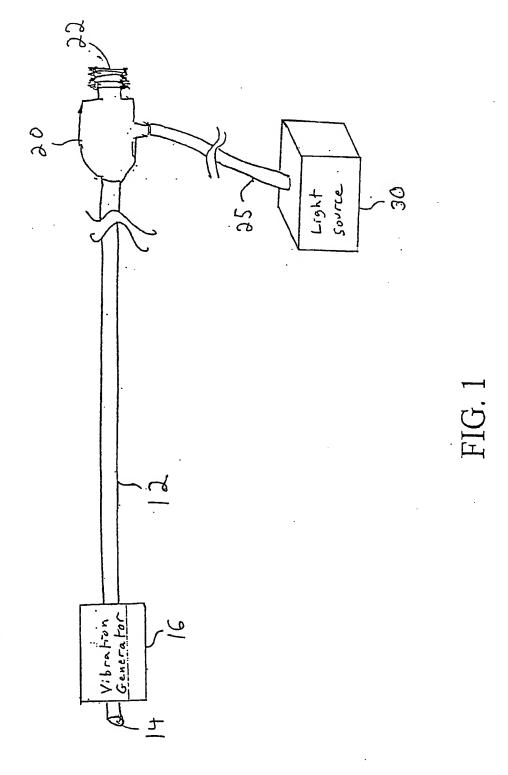
vibrating the distal end of the one or more imaging fibers so as to increase the field of view of the imaged area.

- 11. The method of Claim 10, further comprising placing one or more illumination fibers near the imaged area so as to illuminate the imaged area.
- 12. The method of Claim 10, further comprising locating an imaging device at the proximal end of the one or more imaging fibers for receiving the image signals.
- 13. The method of Claim 12, further comprising using a processor to process the image signals from the imaging device.
- 14. The method of Claim 13, wherein the processor is able to store or display the image.
  - 15. An imaging system for use in surgical procedures, comprising: an imaging channel comprising one or more fibers; and

a motion generator comprising first and second movement elements, the motion generator being operable to cause the first movement element to move relative to the second movement element, the first movement element being coupled to the one or more fibers.

- 16. The imaging system of Claim 15, wherein the first movement element comprises a metal ring.
- 17. The imaging system of Claim 16, wherein the second movement element comprises one or more electrical coils.
- 18. The imaging system of Claim 15, wherein at least one of the first or second movement elements comprises one or more piezoelectric crystals.

- 19. The imaging system of Claim 15, wherein at least one of the first or second movement elements comprises one or more microelectrical mechanical systems.
- 20. The imaging system of Claim 15, wherein the motion generator utilizes ultrasound or frequency modulation.



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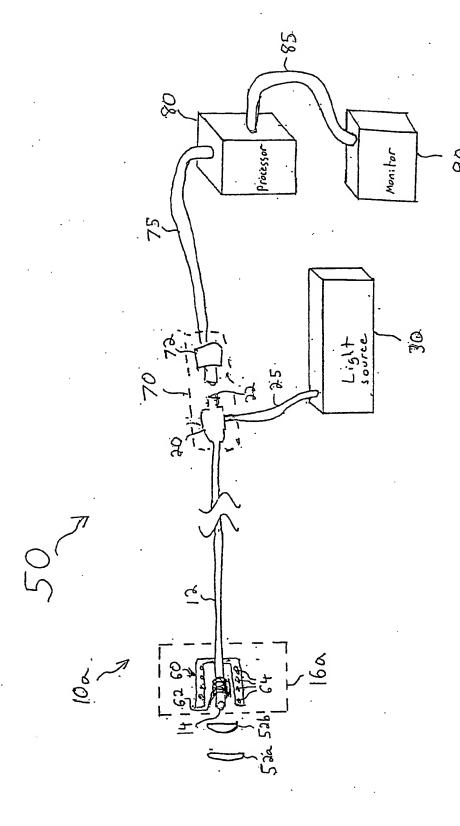


FIG. 2

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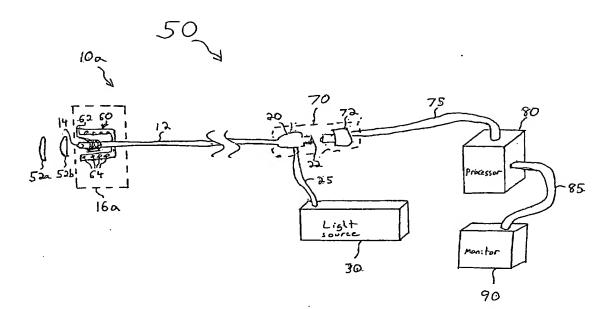
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TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,

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[Continued on next page]

(54) Title: VISION CATHETER



(57) Abstract: A catheter with a small optical fiber or bundle of fibers includes a scanning mechanism constructed with the use of any vibration capable component. Magnetic, piezoelectric or other mechanisms are used to vibrate the end of the fiber and thus create a scanning effect which extends the field of view. This configuration can be used in a catheter with a relatively small diameter. A glass lens or lenses placed in front of the fiber focuses and magnifies the image. A CCD, CMOS, or photodiode camera at the proximal end of the fiber captures the image and transfers it to a computer or processor. A light splitter coupled to a light source provides light through an illumination fiber. The resulting vision catheter is relatively inexpensive and disposable.

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According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

#### EPO-Internal

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
<b>X</b>	US 6 294 775 B1 (SEIBEL ERIC J ET AL) 25 September 2001 (2001-09-25)	1-3,5, 7-9,15, 18-20
A	column 3, line 18 - column 4, line 64 column 7, line 55 - column 15, line 3	4,6,16, 17
X	US 2001/055462 A1 (SEIBEL ERIC J) 27 December 2001 (2001-12-27)	1-3,5, 7-9,15, 18-20
	paragraph '0056! paragraphs '0076! – '0081! paragraphs '0087! – '0090! paragraphs '0110! – '0146!	
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26 January 2005	02/02/2005
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	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	PC1/U3200	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	-	Relevant to claim No.
X	US 6 013 025 A (BONNE ET AL)		1,15
	11 January 2000 (2000-01-11) column 5, line 25 - column 6, line 4		
X	US 4 870 951 A (SUZUKI ET AL) 3 October 1989 (1989-10-03) column 3, line 35 - column 6, line 11 column 9, line 3 - column 10, line 1		1,15
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Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 6294775	B1	25-09-2001	US	2002139920 A1	03-10-2002
US 2001055462	A1	27-12-2001	US US US AU JP WO	2004122328 A1 2004254474 A1 2002064341 A1 7493301 A 2003535659 T 0197902 A2	24-06-2004 16-12-2004 30-05-2002 02-01-2002 02-12-2003 27-12-2001
US 6013025	Α	11-01-2000	US	6306083 B1	23-10-2001
US 4870951	A	03-10-1989	JP JP JP JP JP	6005764 Y2 64031702 U 1037927 A 2059127 C 7095996 B	16-02-1994 27-02-1989 08-02-1989 10-06-1996 18-10-1995

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